11:30 a.m.

879-5 Beta Radiation With Direct Stenting: Final Results of the BRIDGE Trial

Patrick W. Serruys, William Wijns, Ivan de Scheerder, Paul A. van den Heuvel, Wolfgang Rutsch, Helmut D. Glogar, Carlos Macaya, Pierre H. Materne, Heike Vonhausen, Patricia C. Otto-Terlouw, Erasmus Medical Center, Rotterdam, The Netherlands

The BRIDGE study is a multicenter, randomized controlled clinical trial evaluating the acute and long-term efficacy of intravascular brachytherapy (VBT) with P-32 immediately following direct stenting (20 Gy 1 mm inside the coronary wall).
VBT at the time of stent implantation for de novo lesions has not yielded good results and is presently abandoned. We wanted to revisit this approach and have tried to optimize all procedural steps: ideal case selection, use of IIb-IIIa blockers, direct stenting, avoidance of edge damage, source centering, IVUS guided dosimetry and adequate radiation coverage. Patients were randomized to VBT or no-VBT. The sample size has at least 84% power to detect a 50% decrease in loss of MLD as assessed by QCA at 6 months (primary endpoint). The secondary endpoints are clinical and safety outcomes (1, 6 and 12 mths), restenosis (50% diameter stenosis), remodelling and neo-intimal hyperplasia by IVUS, late thrombotic occlusion (up to 12 mths). Inclusion criteria: stable or unstable angina or documented silent ischemia with one or two successfully stented de novo lesions at least 2.5-4.0 mm in diameter and up to 15mm long. Between Feb 2001 and Mar 2002, 112 patients (1.04 lesions/pt) were randomized to VBT or no-VBT at 8 sites in Europe. Of the VBT patients 93% were successfully treated. Baseline characteristics: age 60.5 yrs, male 79.8%, unstable 25.5%, stable angina 68.2%, silent ischemia 5.5%. Pre-procedure (N=81): mean vessel size was 2.84 vs. 2.85 mm, MLD was 0.95 vs. 1.05 mm and lesion length was 10.9 vs. 11.0 mm (VBT vs. no-VBT). Post-procedure: mean vessel size was 2.83 vs. 2.82 mm and MLD was 1.78 vs. 2.04 mm. Stented segment: mean vessel size was 3.04 vs. 3.03 mm, MLD post was 2.69 vs. 2.67 mm, diameter stenosis was 11 vs. 12 % (VBT vs. no-VBT). Irradiated segment (defined by the length of the effective radiation source, full dose prescribed): mean vessel size was 2.98 mm, MLD post was 2.05 mm, diameter stenosis was 32%. MACCE up to 30 days: death 0%, Q-MI 1.8%, non-Q-MI 2.7%, CABG 0%, re-PTCA 0.9% and 1.8% sub-acute occlusion.
The final results, including 12 months follow-up, will be presented during the meeting.

11:45 a.m.

879-6 Sirolimus-Eluting Stent or Intracoronary Brachytherapy to Treat In-Stent Restenosis

Fausto Feres, Juan S. Munoz, Alexandre A. Abizaid, Rodolfo Staico, Luiz A. Mattos, Galo Maldonado, Marinella Centemero, Luiz F. Tanajura, Aurea J. Chaves, Ibraim Pinto, Andrea S. Abizaid, Amanda Sousa, Jose Eduardo M. Sousa, Institute Dante Pazzanese of Cardiology, Sao Paulo, Brazil

Background: Intracoronary Beta-Radiation Therapy (BT) has been shown to be effective to treat in-stent restenosis (ISR) in large randomized clinical trials. Drug- eluting stents (DES) also have been successfully used to treat ISR in small pilot studies. The purpose of this study is to report clinical and angiographic outcomes of patients (Pts) with ISR treated either with balloon angioplasty followed by BT or DES.
Methods: From March 2001 to April 2002, 50 consecutive pts with ISR were treated either with Sirolimus- eluting stent or BT (Novoste,Beta-Cath).The first 25 pts were treated with DES (one or two 18 mm Cypher stent were used per patient) and the second 25 treated with BT (40 mm source). Angiographic quantifications were performed in all pts at baseline (Post) and the follow-up (FUP) (12 months for DES and 6 months for BT).
Results: Clinical FUP was available at 12 months for all pts in DES group and for 22 (88%) in the BT group who completed 6 months FUP. 100% of DES group and 82% of the BT group were free of MACE (TVR, AMI or death)-p=0.04. Angiographic FUP was done in all DES group at 12 months and 86% of the pts in BT group (19/22).

Angiographic Results(mm)	DES(n=25)	BT(n=19)
In-lesion length	13.66±7.80	16.74±3.63
Reference Diameter Post	2.8±0.36	2.70±0.35
MLD Pre	1.05±0.31	1.08±0.34
MLD in-segment Post	2.35±0.37	1.98±0.30*
MLD in-stent Post	2.72±0.31	1.99±0.31*
%DS Pre	62.06±10.71	63.51±8.90
%DS in-segment Post	16.13±8.14	28.54±7.94*
%DS in-stent Post	2.56±9.21	29.73±8.28*
Acute gain	1.67±0.34	0.91±0.43*
Reference Diameter FUP	2.78±0.34	2.62±0.33
MLD in-segment FUP	2.19±0.56	1.49±0.24*
MLD in-stent FUP	2.36±0.57	1.90±0.31*
Late loss in-segment	0.16±0.42	0.49±0.13*
Late los in-stent	0.35±0.45	0.10±0.29*
Angiographic restenosis	1(4%)	3 (15.7%)

* p ≤ 0.05 vs. DES. MLD: minimal lumen diameter. %DS: % Stenosis diameter.
Conclusions: DES group presented better acute and late results (larger MLD post, FUP and acute gain). Although BT group had a smaller late loss in-stent, angiographic restenosis and MACE were smaller in the DES group, because of late loss in-segment in this group was much smaller.

ORAL CONTRIBUTIONS

880FO Featured Oral Session...New Insights in Pharmacology for Percutaneous Coronary Intervention

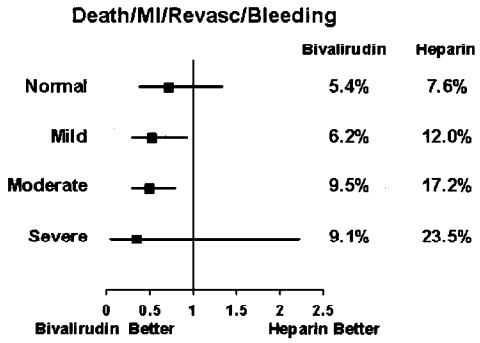
Wednesday, April 02, 2003, 10:30 a.m.-Noon
McCormick Place, Grand Ballroom S100 BC

10:45 a.m.

880FO-2 Bivalirudin Provides Increasing Benefit With Declining Renal Function in Percutaneous Coronary Intervention: A Meta-Analysis of 5,035 Patients Enrolled in Three Randomized Trials

Derek P. Chew, Deepak L. Bhatt, Peter B. Berger, Tim Henry, Peter A. McCullough, Frederick Feit, John A. Bittl, A. Michael Lincoff, Flinders Medical Center, Adelaide, Australia, The Cleveland Clinic Foundation, Cleveland, OH

Background: Chronic kidney disease is associated with an increased risk of both ischemic and bleeding events during PCI. Bivalirudin reduces both bleeding and ischemic complications. We sought to assess the magnitude of benefit in patients stratified by renal function.
Methods: We performed a meta-analysis of three randomized trials (BAT, REPLACE-1 and CACHET) comparing bivalirudin with heparin during PCI in which 5035 pts were enrolled. Stratification by renal function was performed by estimated glomerular filtration rate (eGFR) as determined by the Cockcroft-Gault equation: >90mls/min [n=1578; 31%]; 90-60mls/min [n=2163; 43%], 59-30 mls/min [n=1255; 25%], <30ml/min [n=39; 1%]. Trial specific eGFR strata for death, MI revascularization and hemorrhage were combined with a random-effects model.
Results: Ischemic and bleeding event rates increased with declining eGFR. Across strata, the relative benefit of bivalirudin vs. heparin with respect to ischemic events [>90: 0.79, 90-60:0.73, 59-30: 0.77, <30: 0.81], and bleeding events [>90: 0.45, 90-60:0.40, 59-30: 0.46] was maintained. Consequently, the benefit in terms of absolute ischemic and bleeding events increased with declining renal function (interaction p=0.044).
Conclusion: Renal dysfunction remains a prevalent risk factor for ischemic and bleeding events among patients undergoing PCI. Bivalirudin provides greater absolute benefit in reducing these adverse events in patients with impaired renal function.



11:00 a.m.

880FO-3 A Prospective, Randomized Placebo-Controlled Multicenter Trial Evaluating Fenoldopam Mesylate for the Prevention of Contrast Induced Nephropathy: The CONTRAST Trial

Gregg W. Stone, Peter McCullough, James Tumlin, Hooman Madyoon, Patrick Murray, Andrew Wang, A. Alan Chu, Gary Schaer, Melissa Stevens, Robert L. Wilensky, William W. O'Neill, Norman Lepor, Cardiovascular Research Foundation and Lenox Hill Heart and Vascular Institute, New York, NY

Background. Contrast-induced nephropathy (CIN) is common in pts with baseline chronic renal insufficiency undergoing invasive cardiac procedures, and is a powerful predictor of early and late morbidity and mortality. Fenoldopam mesylate is a selective dopamine-1 agonist that preserves renal medullary blood flow, and has shown promise in small studies in preventing CIN.
We therefore performed a large, multicenter, prospective randomized trial to evaluate this agent in pts at risk for CIN.
Methods. 315 pts at 28 U.S. centers with a baseline creatinine clearance (CrCl) of <60 cc/min not on dialysis undergoing cardiac catheterization ± angioplasty were hydrated and randomized 1:1 to I.V.fenoldopam (0.05 ug/kg/min titrated up to 0.10 ug/kg/min) vs. matching placebo, starting 1 hour prior to angiography and continuing for 12 hours thereafter. Serum creatinine levels were measured at baseline, and at 1, 24, 48 and between 72-96 hours following completion of study drug, and analyzed at a central biochemistry lab. The primary endpoint was the incidence of CIN, defined as an increase in serum cre-